Overview of the Medicare Prescription Drug Benefit
MMA Title I Summary

Background

A. Medicare Prescription Drug, Improvement and Modernization Act of 2003

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 establishes a new voluntary outpatient prescription drug benefit under Part D of title XVIII of the Social Security Act (Act). The prescription drug benefit, referred to as Medicare Part D, as well as an employer subsidy for qualified retiree health plans begins on January 1, 2006. Coverage for the drug benefit will be provided by private prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage plans that offer both prescription drug and health care coverage (known as MA-PD plans). It may also be offered by managed care plans with cost-reimbursement contracts under section 1876 of the Act. We refer to all of these plans in general as Part D plans. These plans must offer a standard drug benefit, but will have the flexibility to vary the drug benefit within certain parameters. Assistance with premiums and cost sharing is provided to eligible low-income beneficiaries. Part D covers many, but not all, of the same drugs that are approved under the Medicaid program, provided they are dispensed by prescription and on an outpatient basis for a medically accepted indication (although selection may be restricted through a plan's formulary).[1]

Medicare Drug Benefit

Standard Benefit
Beginning in 2006, Medicare beneficiaries will have access to the standard drug benefit described below. Although drug plan sponsors may change some of the specifications below, the benefit offered must at least be equal in value to the standard benefit. In 2006, standard coverage includes:

- A monthly premium estimated on average to be about $37 (a beneficiary may pay a higher or lower amount depending upon which PDP or MA-PD the beneficiary selects.
- A deductible of $250
- Coinsurance of 25 percent (or cost-sharing on average equal to coinsurance of 25 percent) up to an initial coverage limit of $2250
- Protection against high out-of-pocket prescription drug costs, with co-pays of generally the greater of $2 for generics and preferred multiple source drugs and $5 for all other rugs, or 5 percent of the price, once an enrollee's out-of-pocket spending reaches a limit of $3,600.

[1] Drugs and biological products that are paid by Medicare Part A or Part B are excluded. In addition, some drugs that may be covered under a state Medicaid plan - such as drugs used to treat anorexia, for example - would not be covered under standard Part D coverage."

Low-Income Benefit

Those beneficiaries with limited savings and low incomes will receive a more generous benefit package, as described below (for 2006):

Beneficiaries with limited savings and incomes below 135 percent of the federal poverty line (which in 2004 was 12,569 for individuals, $16,862 for couples) will receive:

- A $0 deductible
- A $0 premium[2]
- Continuation of coverage beyond the initial coverage limit
- Co-pays of $2 for generics and preferred multiple source drugs and $5 for all other drugs, up to the out-of-pocket limit[3]
- $0 co-pay for all prescriptions once the out-of-pocket limit is reached. The government subsidy for cost-sharing counts toward the out-of-pocket limit.

Beneficiaries with limited savings and incomes below 150 percent of the federal poverty level (which in 2004 was $13,965 for individuals; $18,735 for couples) will receive:

- A sliding scale monthly premium that would be on average $18 for beneficiaries with incomes between 135 percent and 150 percent of the federal poverty level
- A $50 deductible
- Continuation of coverage beyond the initial coverage limit
- Coinsurance of 15 percent up to the out-of-pocket limit . (The government subsidy for cost-sharing counts toward the out-of-pocket limit)
- Copays of $2 for generic drugs and preferred drugs that are multiple source drugs or $5 once the out-of-pocket limit is reached

Alternative Prescription Drug Coverage

Sponsoring organizations may offer coverage of part D benefits through plans that provide (1) coverage, the actuarial value of which is at least equal to the actuarial value of standard prescription drug coverage, (2) access to negotiated prices, and (3) are approved by the Secretary. Such coverage must meet certain other statutorily-defined parameters.

Supplemental Prescription Drug Coverage

Part D plans may provide supplemental prescription drug coverage consisting of cost-sharing reductions and/or optional drugs. However, a PDP sponsor that offers a plan that provides supplemental prescription drug coverage must also offer a prescription drug plan in the area that only provides basic drug coverage. .MA-PD organizations also must offer plans with basic drug coverage or enhanced coverage for no additional supplemental premium, in addition to offering plans with supplemental coverage for an

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[2] Individuals eligible for a full low-income premium subsidy will have a zero premium if they enroll (or are auto-enrolled) in a plan with a monthly premium at or below the low-income premium subsidy amount.

[3] For individuals eligible for full benefits under Medicare and Medicaid ("full-benefit dual eligible individuals") with income under 100% of the federal poverty line, and limited savings, the co-payment is reduced to $1 and $3, and for those full-benefit dual eligible individuals who are residents of nursing homes there is no co-pay.]

additional premium. (Basic coverage is either the statutorily-defined standard benefit or the alternative prescription drug coverage without any supplemental benefits.)

B. Organizational Overview of Part 423

Section 101 of the MMA amended Title XVIII of the Act by inserting a new Part D, which establishes the Medicare Prescription Drug Benefit. We have added a new Part 423 to our regulations at title 42 of the Code of Federal Regulations to implement Part D of the statute.

Subpart A— General Provisions

- **Statutory basis and Roadmap**: Statutory basis for regulations and a listing and general summary of subparts.

- **Definitions:** Commonly used definitions used throughout the regulations.

- **User Fees:** The requirements of section 1857(e)(2) of the Act and 42 C.F.R. §422.6 are extended to PDPs and MA-PD plans for the payment of fees established by CMS for sharing of enrollment-related costs. These fees are currently required of MA plans for the purpose of defraying part of the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1-800-MEDICARE telephone line, community based outreach to support State health insurance assistance programs (SHIPs), and other enrollment and information activities required under section 1851 of the Act and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L.No. 101-508).

Subpart B— Eligibility, Election and Enrollment

- **Enrollment Periods for Part D:** Section 1860D-(1)(b)(1)(B)(iii) of the Act directs CMS to establish three coverage enrollment periods for Part D: the initial enrollment period, the annual coordinated election period and special enrollment periods.

  - The initial enrollment period when a beneficiary first becomes eligible for Part D is similar to the initial enrollment period established for Part B. For the start of the Part D program in 2006, individuals who are already Part D eligible as of November 15, 2005 will have from November 15, 2005 until May 15, 2006 to enroll in a Part D plan.

  - Generally, the annual coordinated election period is from November 15 – December 31st of each year. However, for the beginning of the Part D program,

the annual coordinated election period begins on November 15, 2005 and is extended to May 15, 2006.

- Special enrollment periods will also be provided for certain circumstances, such as changes in residence, and in other circumstances we find necessary.

- **Automatic enrollment of full-benefit dual eligible beneficiaries in part D plans:** Section 1860D-1(b)(1)(C) of the Act directs CMS to establish a process to automatically enroll, on a random basis where possible, full-benefit dual eligible beneficiaries who have not enrolled in a Part D plan into a prescription drug plan that has a monthly beneficiary premium that does not exceed the low income premium subsidy amount. CMS will perform the auto-enrollment function. To ensure that there is no coverage gap, CMS will perform the auto-enrollment in the fall of 2005 as soon as eligible Part D plans are known, and auto-enrollment will be effective January 1, 2006. After 2006, full benefit dual eligible individuals will be auto-enrolled into plans as soon as their Medicare Part D eligibility is determined. Dual eligible beneficiaries will have an opportunity to opt out of their PDP plan at any time if plan does not meet the needs of that beneficiary.

- **Late Enrollment Penalty:** As established under section 1860D-13(b) of the Act, a Part D eligible individual is subject to a late enrollment penalty, in the form of increased premiums, if s/he fails to maintain creditable prescription drug coverage for a period of 63 days or longer. Creditable prescription drug coverage means drug coverage that is actuarially equivalent to Part D.

- **Information Provided to Beneficiaries**: As established under 1860D-1(c)(1) of the Act, CMS will establish a comprehensive set of activities to broadly disseminate information about Part D coverage to individuals who are eligible or prospectively eligible for Part D benefits. This will include developing a price comparison tool, similar to the price comparison tool currently available for Medicare-approved discount drug cards, on www.medicare.gov in order to make comparative information about Part D plans' negotiated prices available to beneficiaries.

- **Marketing Procedures:** Section 1860D-1(b)(1)(B)(vi) directed CMS to establish similar marketing requirements as provided for Medicare Advantage plans. In the final rule, CMS defines marketing materials, standards for PDP marketing, and the process for marketing review and approval

- **Disclosure of Creditable Status of Drug Coverage:** Section 1860D-13(b)(6) of the Act requires certain entities (such as a former employer) that provide prescription drug coverage to Part D eligible individuals to disclose to those individuals whether or not the coverage that they provide is creditable coverage, as defined by CMS. We will require the entities to provide to all Part D eligible individuals enrolled in or seeking to enroll in the coverage offered by the entity whether their coverage meets actuarial requirements as provided by CMS. In the

final rule, we also outline when the entities must provide such disclosure to beneficiaries. Entities will also be required to inform CMS as to the status (i.e. creditable or non-creditable) of this coverage.

Subpart C— Benefits and Beneficiary Protections

- **Requirements for prescription drug coverage:** Establishes requirements for qualified prescription drug coverage to be offered by Part D plans.

- **Prescription drug service areas:** Establishes requirements for prescription drug service areas**.** On December 6, 2004, we announced the establishment of 26 MA regions and 34 PDP regions in separate guidance that can be viewed at www.cms.hhs.gov/medicarereform/mmaregions.

- **Pharmacy networks:** Establishes minimum standards for the creation of Part D plan pharmacy networks. The purpose of these standards, which are based on those used under the TRICARE Retail Pharmacy program, is to ensure that enrollees have access to a sufficient number of pharmacies dispensing covered Part D drugs directly to them. We also establish network standards for access to home infusion pharmacies, long-term care pharmacies and Indian/Tribal/Urban facilities.

- **Formulary development:** Establishes requirements for formulary development for those Part D plans that plan to use a formulary.

- **Information dissemination requirements:** Establishes requirements regarding the dissemination of Part D information to enrollees and prospective enrollees by Part D plans. Part D sponsors must provide information about service areas, benefits, cost sharing, formulary, pharmacy access, and other aspects of the coverage available under their Part D plans. This information must be provided to current and prospective enrollees in writing, as well as on a plan website and upon request through a toll-free call center. Such information dissemination by plans will facilitate informed decisions by Part D eligible individuals about their Part D coverage options.

- **TrOOP:** - True out-of-pocket costs. Beneficiary "costs" for drugs count towards satisfying the threshold in out-of-pocket costs that must be reached before the catastrophic benefit becomes available. These costs only count as TrOOP when they are paid for by the beneficiary, another person[4] on their behalf (such as a family member), a qualified SPAP or a bona fide charity. We note that the deductible does not have to be satisfied by out-of-pocket payments, it can be paid by insurance or another payer such as Indian Health Service. In the final rule, we

[4] These costs count toward TrOOP when paid by a "person" other than insurers or otherwise, group health plans, or similar third party payment arrangements. "Person" is defined broadly to include any individual (including non-family members), corporations such as pharmaceutical manufacturers, associations, etc.

clarify definitions of payments that may count toward or must be excluded from the calculation of TrOOP.

Subpart D— Drug Utilization Management, Quality Assurance, and Medication Therapy Management

- **Quality and management programs:** The major section of this subpart deals with quality assurance measures and systems, drug utilization management, and medication therapy management programs. The regulations require that all Part D plans, except PFFS plans, have drug utilization management and medication therapy management programs. Quality assurance measures, such as drug utilization review, are population-based, while medication therapy management optimizes therapeutic outcomes through providers working with targeted individuals.

- **Consumer satisfaction surveys and accreditation:** Other provisions of this subpart deal with consumer satisfaction surveys for Part D plans and deeming of accreditation organizations.

- **Electronic Prescription Standards**: Part D sponsors will need to support final e-prescribing standards once final standards are effective. These standards will be issued through a separate rulemaking.

Subpart F— Submission of Bids, Premiums and Related Information and Plan Approval

- **Risk bids:** CMS will not accept risk bids from entities bidding or offering fallback plans in most cases. (A "fallback plan" is a Part D plan that does not assume risk and is generally paid by CMS on a cost basis.) PDPs may submit limited risk bids, but these will not be accepted if a sufficient number of full risk bids are received and approved for the same region.

- **Bid submission:** The risk bid submission process and rules are synchronized with Medicare Advantage. All bids are standardized on the expected costs for the average Medicare beneficiary in the Part D plan's region.

- **CMS authority to review and negotiate bids:** CMS has authority similar to the authority that the Office of Personnel Management (OPM) has to review and negotiate bids submitted by insurers, in addition to its general negotiation authority. However, this authority must be read in conjunction with the "non-interference" provision of § 1860D-11(i)(1), which prohibits the federal government, in carrying out Part D, from interfering in negotiations between drug manufacturers, pharmacies, and Part D plans. We interpret the non-interference provision as prohibiting CMS from setting the price of any particular drug or from

requiring an average discount in the aggregate on any group of drugs, but allowing justification of aggregate price levels. Although CMS will not negotiate regarding the price levels of drugs, we will negotiate regarding the level of the overall bid and will exercise our authority to deny a bid if we do not believe that the bid and its underlying drugs prices reflect appropriate market rates.

- **Enrollee premiums:** Enrollee premiums are based on a national percentage of the national average monthly bid amount with adjustments up or down depending on the competitive standing of the plan bid relative to this national average.

- **Private fee-for-service (PFFS) and fallback plans:** Special rules for plans offered by private fee-for-service (PFFS) and fallback plans dictate different bidding, negotiation and approval processes.

Subpart G— Payments To PDP And MA-PD Plans

- **Monthly "direct subsidy":** PDPs and MA-PD plans receive a monthly "direct subsidy" equal to their bid amount, risk-adjusted for enrollee health status and minus the enrollee premium.

- **New prospective risk adjustment model:** The risk adjustment requires development of a new prospective risk adjustment model based on the relationship of drug spending to medical diagnoses. CMS will initially tie medical claims from MA and FFS beneficiaries to determine the Part D risk scores. We will also look at the relationship between drug spending and low-income and institutionalized status.

- **Monthly interim payments:** Monthly interim payments will be made on either estimated or actual reinsurance subsidies.

- **Monthly low-income subsidy payments:** Monthly low-income subsidy payments will be made based on 1) enrollee premiums and 2) either estimated or actual cost sharing incurred by low-income subsidy-eligible individuals (see Subpart P).

- **Risk sharing arrangements:** Risk sharing arrangements based on allowable costs (net of all price concessions) in specified symmetrical risk corridors will be calculated and paid (or recovered) following the end of the coverage year.

- **Reconciliation processes:** Extensive reconciliation processes will be required to settle prepaid to actual enrollment, risk adjustment, low-income subsidy, and reinsurance payments (in that order) prior to calculation of risk sharing.

Subpart I—Organization Compliance with State Law and Preemption By Federal Law

- **State licensure:** PDPs must be state licensed as risk-bearing entities.

- **Unlicensed PDPs:** Unlicensed PDPs may obtain a federal waiver based on certain criteria:

    1. State failed to act on application on a timely basis
    2. State licensure was denied based upon discriminatory treatment
    3. State denial based upon solvency standards different from federal standards

- **Federal solvency standards:** Federal solvency standards for non-licensed entities have been developed and released for public comment after consultation with the National Association of Insurance Commissioners.

Subpart J—Coordination with Plans and Programs that Offer Prescription Drug Coverage

- **Definition of a State Pharmaceutical Assistance Program (SPAP)**: Establishes requirements regarding what constitutes a State program that may be defined as an SPAP and therefore may wrap around the Part D benefits and have its cost-sharing assistance count toward TrOOP. An SPAP is a State program that provides supplemental drug coverage to individuals based on financial need, age, or medical condition (and not based on current or former employment status) and does so without any Federal program funding. We will provide "seed" money in 2005 and 2006 to facilitate coordination of enrollment, coverage, and payment between SPAPs and Part D plans.

- **Application of Part D rules to certain Part D plans:** Generally applies Part D requirements to MA-PD plans, employer-sponsored group prescription drug plans and MA-PD plans, and PACE organizations and cost plans offering Part D benefits. Establishes processes for the request and application of waivers and modifications of Part D rules to MA plans, employer-sponsored group prescription drug plans, cost plans, and PACE organizations.

- **Application of Medicare secondary payer (MSP) provisions**: Applies MSP requirements applicable to MA organizations and MA plans to Part D sponsors and Part D plans.

- **Coordination of benefits with other providers of prescription drug coverage**: Establishes requirements for the coordination of benefits between Part D plans and SPAPs and entities providing other prescription drug coverage for the payment of premiums and coverage, as well as for payment for supplemental

prescription drug benefits. Detailed coordination of benefits requirements will be issued by the July 1, 2005 statutory deadline.

Subpart K— Application Procedures and Contracts with Part D Sponsors

- **Application process:** Description of process to apply and gain approval for a contract as a Part D sponsor

- **Terms of the contract:** The terms of the contract including: conditions necessary to contract as a Part D sponsor, contract provisions, effective date and term of contract

- **Requirements in contracts:** Requirements for provisions that must be included in Part D sponsor contracts with other entities.

- **Termination of the contract:** Instructions for non-renewal of contract or termination of the contract by CMS or the Part D sponsor.

Subpart L— Effects of Change of Ownership or Leasing of Facilities

- **Change of ownership:** Description of what constitutes change of ownership with or without novation agreement.

- **Effect of changing ownership:** Effect of changing ownership on the PDP sponsor's contract with CMS.

- **Leasing facilities:** Description of effect of leasing all or part of its facilities to another entity on the PDP sponsor's contract with CMS.

Subpart M— Grievances, Coverage Determinations and Appeals

- **Similar to the Medicare Advantage (MA) program:** In general, the procedures governing grievances, coverage determinations, redeterminations, reconsiderations, and appeals are the same as those that apply to the Medicare Advantage (MA) program.

- **Grievances:** Part D plans are required to establish a process for hearing and resolving enrollees' grievances in a timely manner, and maintain records on the number of grievances they process. The grievance process is not as comprehensive or detailed as the appeals process, and generally is an internal plan process. Quality of care issues may be processed by plans or Quality Improvement Organizations.

- **Coverage Determinations:** Plans are also required to establish a coverage determination process that provides enrollees with the opportunity to obtain medically necessary Part D drugs. We expect that the most common type of coverage determination will involve exceptions requests. If a plan utilizes a formulary to manage its Part D drug benefits, it must have procedures in place that ensure that Part D enrollees have access to medically necessary Part D drugs that are not included on its formulary. Plans are also required to maintain exceptions procedures that allow an enrollee the opportunity to obtain a drug at a more favorable cost-sharing level. When an enrollee requests an exception, the plan's decision is considered a coverage determination, which (if unfavorable to the enrollee) may be appealed.

- **Notice to Beneficiaries:** Subpart M also requires plans to arrange with network pharmacies to provide notice to enrollees explaining how enrollees can obtain a coverage determination, including an exception, if they disagree with the information provided by the pharmacist.

- **Appeals:** Once an enrollee receives an unfavorable coverage determination, he or she may request an appeal. There are five levels of appeal: redetermination by the Part D plan, reconsideration by the Independent Review Entity (IRE), hearing with an administrative law judge (ALJ), review by the Medicare Appeals Council (MAC), and review by a Federal district court. If an enrollee receives an unfavorable coverage determination, he or she may request a standard or expedited redetermination with the plan depending on the enrollee's health condition.

Subpart N— Medicare Contract Determinations and Appeals

- **Procedures:** Description of procedures for making and reviewing the determination that an entity is not qualified to enter into a Part D sponsor 's contract, the determination to terminate a Part D sponsor's contract or a determination not to renew a Part D sponsor.

- **Reconsideration:** Reconsideration applicability, rights and determinations.

- **Hearings:** Rights and process for hearing.

Subpart O— Intermediate Sanctions

- **Sanctions:** Types of sanctions, basis and procedures for imposing sanctions.

- **Civil money penalties:** Maximum amount of civil money penalties imposed by CMS.

Subpart P— Premiums and Cost-Sharing Subsidies for Low-Income Individuals

- **Eligibility for subsidy**: The first section, 42 CFR § 423.773, establishes the qualifying criteria for a subsidy eligible individual. Within the definition of subsidy eligible individuals are three subgroups: Full subsidy eligible individuals, individuals treated as full subsidy eligible, and other low-income subsidy individuals. The qualifying criteria for each of these groups are defined in this section of the regulation.

- **Eligibility determinations:** Section 42 CFR § 423.774 discusses the requirements regarding the low-income subsidy determination, redetermination, and application process. This section of the regulation specifies that SSA or the States (under a State plan for Medicaid), are responsible for determining if an individual is eligible for the low-income subsidy.

- **Amount of Premium Subsidy:** Section 42 CFR 423.780 establishes how the premium subsidy amount is determined for the full subsidy eligible population and establishes the sliding scale to be applied to premiums for the other low-income subsidy eligible group. The premium subsidy amount is the lesser of the monthly beneficiary premium for basic coverage under the Part D plan[5] selected by the beneficiary, or the greater of the low-income premium benchmark amount for a PDP region or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage.

- **Amount of Cost–Sharing Subsidy:** The next section, 42 CFR § 423.782, provides the degree to which cost sharing is subsidized based upon the subsidy eligible groups. It clarifies the cost sharing reductions for full benefit dual eligible individuals based on whether an individual is at or below 100% of the FPL, above 100% FPL, or institutionalized. Also included in this section are the rules regarding the reduction to the annual deductible, the application of the 15% coinsurance limit for other low-income subsidy eligible individuals, and the nominal copayment obligations for the full-subsidy eligible population. All low-income subsidy eligible individuals have nominal copayment obligations at the catastrophic level.

- **Administration of Subsidy:** The final section of Subpart P, 42 CFR §423.800, provides the responsibilities of the Part D plans and CMS regarding the administration of the subsidy program. It establishes the responsibilities of the PDP when reducing the cost sharing and premiums associated with a subsidy-eligible individual as well as the requirements of the Part D plan when an

[5] For MA-PD plans the monthly beneficiary premium is the MA monthly prescription drug beneficiary premium, which is the basic premium reduced for any rebated dollars used to reduce the Part D premium.

individual and PDP is notified of subsidy eligibility after the beneficiary has already accessed the plan's benefits.

Subpart Q— Fallback Plans

- **Bid submission:** Fallback applicants will submit bids (proposals) pursuant to a separate contracting process that is conducted after the risk bidding process.

- **Bid review:** In reviewing and negotiating fallback bids, CMS will interpret the non-interference provision as prohibiting CMS from setting the price of any particular drug or from requiring an average discount in the aggregate on any group of drugs, but allowing both justification of aggregate price levels and negotiations around targeted price levels for categories of drugs as reference points for performance-based contracting with fallback plans.

- **Fallback plan availability:** Fallback plans will be offered in any region, or local area of any region, in which there is not a choice of at least two qualifying plans, one of which must be a stand-alone PDP. An MA-PD may only be counted as qualifying if it is open to enrollment and not operating under a capacity waiver, or an enrollment waiver, such as a special needs plan. A PDP may only be counted as qualifying if it is not operating under a restricted enrollment waiver, such as an employer-sponsored plan.

- **Premiums:** Premiums for enrollees in fallback plans that are not deducted from federal benefits, such as Social Security checks, will be collected by fallback plans and then deducted from fallback plan management fees by CMS.

- **Same terms and conditions as at-risk PDPs:** Fallback plans will be subject to most of the contract terms and conditions applicable to at-risk PDPs, with certain specified exceptions such as contract term, marketing restrictions and performance-based payment.

Subpart R— Payments to Sponsors of Retiree Prescription Drug Plans

- **Requirements to Apply for the Retiree Drug Subsidy for Plan Sponsors.** In order for a sponsor to receive a retiree drug subsidy, its retiree plan must meet the definition of a qualified retiree prescription drug plan., This means that the a plan must meet the definition of employment-based retiree health coverage and must comply with certain other requirements. A plan sponsor that wishes to be paid the Medicare retiree drug subsidy must apply annually for the subsidy and must attest that the drug benefits of the retiree plan are actuarially equivalent to the defined standard Part D drug coverage. The sponsors must maintain sufficient records to support the attestation and document its prescription drug costs in order for HHS to be able to conduct an audit.

- **Notification of Creditable Coverage.** For a sponsor's plan to meet the definition of a qualified retiree prescription drug plan, the sponsor must provide for disclosure to its retirees of whether the retiree plan coverage is "creditable coverage" in accordance with the requirements set forth in Subpart B.

- **Retiree drug subsidy amounts.** Sponsors will be reimbursed for 28% of the annual allowable costs of providing prescription drug coverage to the plan enrollees who are qualifying covered retirees (Medicare beneficiaries who are eligible to enroll in Part D, but are not enrolled). Costs that are counted toward the subsidy include dispensing costs of Part D drugs, but not administrative costs of the sponsor. Discounts, rebates and chargebacks must be subtracted from the costs. The sponsor must be able to account for the allowable costs for each qualifying covered retiree. Random follow-up audits will be conducted to ensure accuracy of the payments. The first payments are to be made in 2006.

Subpart S— Special Rules for States-Eligibility Determinations for Low-Income Subsidies

- **State requirements:** Section 42 CFR § 423.904 explains the general requirements states must follow when making eligibility determinations and redeterminations for the low-income subsidy program. It also requires states to screen low-income subsidy eligible individuals for Medicare Savings Programs (MSPs) and offer enrollment into these programs if they are determined eligible. This section further requires states to begin accepting applications for the low-income subsidy no later than July 1, 2005 and provide information regarding income levels to CMS so that CMS can provide Part D plans with a list of individuals who qualify for the low-income subsidy and the amount of subsidy.

- **Medicare as primary payer:** Specifies that, for persons eligible for Part D, medical assistance is not available for Medicaid covered drugs that could be covered under Part D. Medicare is the primary payer. Section 42 CFR § 423.906 specifies that states receive the regular Federal match for administrative costs associated with determining subsidy eligibility. This section of the regulation also explains that states may provide coverage for outpatient drugs if the drugs are not covered by Part D, in the same manner as provided for non-full benefit dual eligible individuals or through arrangements with the Part D plans.

- **Grant funds for medical assistance:** Section 42 CFR § 423.907 of the regulation specifies the financial assistance territories may provide for their low-income individuals, since individuals residing in the territories do not qualify for the low-income premium and cost-sharing subsidies under section 1860D-14 of the Act. This section of the regulation provides the territories with the Medicaid state plan requirements territories must implement in order to receive increased grants under sections 1108(f) and 1108(g) of the Act.

- **State monthly contribution:** And finally, 42 CFR § 423.908 and § 423.910 provide the states' requirements regarding their contribution towards the costs of drug benefits being assumed by Medicare. 42 CFR § 423. 910 details the calculation of the monthly phased-down amounts states will contribute towards Medicare's prescription drug costs for full-benefit dual eligible individuals, as well as the state's data reporting requirements associated with the phased-down state contribution.

Subpart T— Conforming Changes to Other Regulations (than §423)

- **Prohibition on Medigap policies:** Sales of Medigap policies with drug coverage (including standardized plans H, I and J) are prohibited as of January 1, 2006. (Sales in waiver states are also prohibited.) All issuers of Medigap policies with drug coverage are required to send notices to all policyholders regarding whether the policies are, or are not, creditable prescription drug coverage, and what the beneficiaries' options are. We will publish final model disclosure notices separately from this final regulation.

- **Impact on PACE organizations:** We outline the way in which the Part D prescription drug benefit will impact PACE organizations and provide guidance for implementing the Part D prescription drug benefit through PACE plans. Section 1860ED-21(f) of the Act specified that PACE organizations that provide Part D coverage be treated in a *similar* manner to MA-PD local plans with respect to the offering of Part D coverage. The legislation also allows the Secretary to waive provisions that duplicate or conflict with provisions otherwise applicable to PACE plans or as may be necessary to improve the coordination with the benefits under Part D and PACE

- **Impact on § 1876 Cost Plans**: We have clarified that Part D will be offered somewhat differently by cost plans. (1) Cost plans that choose to offer qualified Part D coverage under § 417.440(b)(2) may do so only by offering qualified Part D coverage as an optional supplemental benefit; (2) Cost plans that offer qualified Part D coverage must offer basic prescription drug coverage. A cost plan that offers basic prescription drug coverage may offer additional qualified Part D coverage choices; (3) A cost plan that does not offer qualified Part D coverage under § 417.440(b)(2) may offer non-qualified drug coverage that is not reimbursed under this Part or Title.

- **Adding Prescription Drugs to the physician self-referral prohibition:** We have modified this definition because we believe that referrals for Part D drugs are subject to the same risk of over-utilization and anti-competitive behavior as referrals for Part B drugs when a financial relationship exists between the referring physician and the entity furnishing the drugs.